

REMARKS

I. PRELIMINARY REMARKS

Claims 39, 50 and 54 have been amended. No claims have been added or canceled. Claims 1, 3, 4, 6-16, 18-28, 33, 36, 37, 39 and 41-62 remain in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

Applicant notes with appreciation that claims 1, 2, 4, 6-16, 18-28, 33, 36, 37 and 49 have been allowed.

II. CLAIMS 39, 41-48 AND 54-62

A. The Claimed Combinations

Independent claim 39 calls for a combination of elements comprising “a surgical probe including ... an inflatable, **energy transmitting therapeutic element that causes tissue to be heated** associated with the distal portion of the shaft, an infusion lumen ... and a ventilation lumen” and “a cooling fluid source ... adapted to ... **continuously infuse cooling fluid to a volume within** the inflatable, energy transmitting therapeutic element by way of the infusion lumen **and draw cooling fluid from the volume within** the inflatable, energy transmitting therapeutic element by way of the ventilation lumen **during a tissue heating procedure.**” Claims 41-48 depend from claim 39 and including, *inter alia*, the combination defined by claim 39.

Independent claim 54 calls for a combination of elements comprising “a surgical probe including ... an inflatable, energy transmitting therapeutic element **that causes tissue to be heated**” and “a cooling fluid source ... adapted to maintain pressure within the inflatable therapeutic element at a predetermined level and to **continuously infuse and ventilate cooling fluid to and from a volume within** the inflatable, energy

transmitting therapeutic element **during a tissue heating procedure.**" Claims 55-62 depend from claim 54 and including, *inter alia*, the combination defined by claim 54.

B. Rejections Based Primarily on the Saab '392 Patent

1. The Rejections

Claims 39, 41-43 and 54-57 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,624,392 to Saab ("the Saab '392 patent"). Claims 44 and 58 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Saab '392 patent and U.S. Patent No. 5,255,678 to Deslauriers ("the Deslauriers '678 patent"). Claims 46-48 and 60-62 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Saab '392 patent and U.S. Patent No. 5,403,311 to Abele ("the Abele '311 patent"). The rejections under 35 U.S.C. §§ 102 and 103 are respectfully traversed with respect to the claims as amended above. Reconsideration thereof is respectfully requested.

2. Claims 39, 41-43 and 54-57

The Saab '392 patent is directed to a heat transfer catheter that may be used to heat or cool tissue by supplying heat transfer fluids to internal body sites. [Column 1, lines 17-22.] The Saab '392 patent does not, however, teach or suggest continuously infusing and ventilating cooling fluid to and from a volume within an inflatable, energy transmitting therapeutic element that causes tissue to be heated during a tissue heating procedure. For example, the catheter illustrated in Figure 3 includes a balloon segment 72 that is connected to an inlet lumen 64 and an outlet lumen 68. Heat transfer fluid that is above, below, or the same temperature as normal body temperature (column 9, lines 42-44) passes through the inlet and outlet lumens 64 and 68 on its way to and from the balloon segment 72. The catheter may also include a tube 74 within lumen 64. The Saab '392 patent indicates that the tube 74 may comprise a catheter carrying

“microwave antennas, lasers, ultrasound probes, induction coils, and electric heating elements.” [Column 12, lines 38-47.]

Referring first to those instances where the balloon segment 72 is receiving heated heat transfer fluid, and assuming for the sake of argument that the Saab balloon segment 72 could be considered an “inflatable, energy transmitting therapeutic element that causes tissue to be heated” when the balloon segment is receiving heated fluid, the Saab system does not continuously infuse and ventilate cooling fluid to and from a volume within balloon segment during tissue heating procedures that involve heated fluid. This would also be true if one of the “microwave antennas, lasers, ultrasound probes, induction coils, and electric heating elements” was located within the balloon segment 72 and being used to heat fluid within the balloon segment so that the balloon segment could heat tissue. [Note that the Saab ‘392 patent is *silent* with respect to the relative positions of these devices and the balloon segment 72.]

Alternatively, in those instances where the balloon segment 72 is receiving cooled heat transfer fluid during a tissue heating procedure, the balloon segment is not the structure that is heating the tissue. The tissue would instead be heated by one of the “microwave antennas, lasers, ultrasound probes, induction coils, and electric heating elements” and no cooling fluid is supplied to, and ventilated from, a volume within these devices. [Note that there is no indication that that the balloon segment 72 electrically conductive or otherwise capable of allowing current to pass therethrough.]

As the Saab ‘392 patent fails to teach or suggest each and every element of the respective combinations recited in independent claims 39 and 54, applicant respectfully submits that claims 39, 41-43 and 54-57 are patentable thereover and that the rejection under 35 U.S.C. § 102 should be withdrawn.

3. Claims 44, 46-48, 58 and 60-62

Turning to the rejections under 35 U.S.C. § 103, applicant respectfully submits that the Deslauriers ‘678 and Abele ‘311 patents fail to remedy the above-identified deficiencies in the Saab ‘392 patent, that claims 44, 46-48, 58 and 60-62 are patentable

for at least the same reasons as independent claims 39 and 54, and that the rejections of claims 44, 46-48, 58 and 60-62 under 35 U.S.C. § 103 should be withdrawn.

C. Rejections Based Primarily on the Combined Teachings of the Stern '470 and Saab '392 Patents

1. The Rejections

Claims 39, 41-43 and 54-57 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of U.S. Patent No. 5,443,470 to Stern ("the Stern '470 patent") and the Saab '392 patent. Claims 44 and 58 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Stern '470 patent, the Saab '392 patent and the Deslauriers '678 patent. Claims 46-48 and 60-62 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Stern '470 patent, the Saab '392 patent and the Abele '311 patent. Claims 45 and 59 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Stern '470 patent, the Saab '392 patent and U.S. Patent No. 5,047,028 to Qian ("the Qian '028 patent"). The rejections under 35 U.S.C. § 103 are respectfully traversed with respect to the claims as amended above. Reconsideration thereof is respectfully requested.

2. Claims 39, 41-43 and 54-57

As illustrated in Figures 1-3, the Stern '470 patent discloses an ablation device that includes an inflatable balloon 14 with a conductive outer surface 35 that is used to heat tissue. The Stern '470 patent also discloses ablation devices with individually controllable electrode segments on the outer surface of an inflatable balloon. [See Figures 4a and 4b.] In contrast to the inventions defined by independent claims 39 and 54, the Stern '470 patent does not teach or suggest continuously infusing and ventilating cooling fluid to

and from a volume within an inflatable, energy transmitting therapeutic element during a tissue heating procedure.

Applicant respectfully submits that the Saab '392 patent fails to remedy this deficiency in the Stern '470 patent. Although the Saab '392 patent does teach the use of cooling fluid, it does not teach or suggest supplying cooling fluid to a structure (such as the Stern balloon) that is actually heating the tissue. As noted above, the fluid within the Saab balloon segment is either filled with hot fluid or, in those instances when it receives cooling fluid, some other device is actually heating the tissue.

As the Stern '470 and Saab '392 patents fail to teach or suggest the respective combinations of elements recited in independent claims 39 and 54, whether viewed alone or in combination, applicant respectfully submits that the rejection of claims 39, 41-43 and 54-57 under 35 U.S.C. § 103 should be withdrawn.

3. Claims 44-48 and 58-62

Turning to the rejections under 35 U.S.C. § 103, applicant respectfully submits that the Deslauriers '678, Abele '311 and Qian '028 patents fail to remedy the above-identified deficiencies in the proposed combination of the Stern '470 and Saab '392 patents, that claims 44-48 and 58-62 are patentable for at least the same reasons as independent claims 39 and 54, and that the rejections of claims 44-48 and 58-62 under 35 U.S.C. § 103 should be withdrawn.

III. CLAIMS 50-53

A. The Claimed Combinations

Independent claim 50 calls for a combination of elements comprising "a relatively short, relatively stiff shaft," "means, associated with the distal portion of the shaft, for inflating and transmitting current to tissue at a level sufficient to cause the formation of lesions without substantial liquid perfusion" and "means for continuously infusing and

ventilating cooling fluid to and from a volume within the means for inflating and transmitting current.” Claims 51-53 depend from claim 50 and including, *inter alia*, the combination defined by claim 50.

B. The Rejections

Claims 50 and 53 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,443,470 to Stern (“the Stern ‘470 patent”). Claims 51 and 52 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Stern ‘470 patent and the Deslauriers ‘678 patent. The rejections under 35 U.S.C. §§ 102 and 103 are respectfully traversed with respect to the claims as amended above. Reconsideration thereof is respectfully requested.

C. Discussion

The Stern ‘470 patent discloses an ablation device that includes an inflatable balloon with a conductive outer surface (or individually controllable electrode segments on the outer surface) that is used to heat tissue. [See Section II-C-2 above.] In contrast to the invention defined by independent claim 50, however, the Stern ‘470 patent does not teach or suggest “means for continuously infusing and ventilating cooling fluid to and from a volume within [a] means for inflating and transmitting current.”

As the Stern ‘470 patent fails to teach or suggest each and every element of the combination recited in independent claim 50, applicant respectfully submits that claims 50 and 53 are patentable thereover and that the rejection under 35 U.S.C. § 102 should be withdrawn.

Turning to claims 51 and 52, applicant respectfully submits that the Deslauriers ‘678 patent fails to remedy the above-identified deficiencies in the Stern ‘470 patent, that claims 51 and 52 are patentable for at least the same reasons as independent claim 50, and that the rejection of claims 51 and 52 under 35 U.S.C. § 103 should be withdrawn.

IV. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

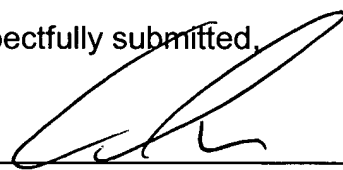
If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

1/23/24
Date

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Respectfully submitted,



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